

## PRE-APPEAL BRIEF REQUEST FOR REVIEW

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**Rajesh Saini**

Docket Number:

**2001-IP-005484U1P1**

Application Number:

**10/736,339**

Art Unit:

**1715**

Conf. Number:

**3700**

Filing Date:

**December 15, 2003**

Examiner:

**Elena Tsoy Lightfoot**

Title:

**On-the-Fly Coating of Acid-Releasing Degradable Material Onto a Particulate**

☒ Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

☒ This request is being filed with a notice of appeal.

☒ The review is request for the reason(s) stated on the attached sheet(s).  
Note: No more than five (5) pages may be provided.

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

I am the

☐ applicant / inventor

☐ assignee of record of the entire interest.

See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed

☒ attorney or agent of record or acting under 37 CFR 1.34.

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May 25, 2011

| <b>UNITED STATES PATENT AND TRADEMARK OFFICE</b>                                             |                                             |                              |
|----------------------------------------------------------------------------------------------|---------------------------------------------|------------------------------|
| <b>PRE-APPEAL BRIEF</b>                                                                      |                                             |                              |
| First Named Inventor:<br><b>Rajesh Saini</b>                                                 | Docket Number:<br><b>2001-IP-005484U1P1</b> |                              |
| Application Number:<br><b>10/736,339</b>                                                     | Art Unit:<br><b>1715</b>                    | Conf. Number:<br><b>3700</b> |
| Filing Date:<br><b>December 15, 2003</b>                                                     | Examiner:<br><b>Elena Tsoy Lightfoot</b>    |                              |
| Title:<br><b>On-the-Fly Coating of Acid-Releasing Degradable Material Onto a Particulate</b> |                                             |                              |

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

The following Pre-Appeal Brief Request for Review ("Request") is being filed in accordance with the provisions set forth in the Official Gazette Notice of July 12, 2005 ("OG Notice"). Pursuant to the OG Notice, this Request is being filed concurrently with a Notice of Appeal and the applicable fee. Appellant respectfully requests reconsideration of the application in light of the remarks set forth below.

**REMARKS**

Claims 42-61 are pending in the application, and all claims stand rejected. No amendments were filed with the response filed on April 18, 2011 in response to the February 25, 2011 Final Office Action.

Appellants assert that the Final Office Action improperly maintained the following rejections:

- Claims 42-48, 55-59, and 61 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,209,643 to Nguyen *et al.* (hereinafter "*Nguyen*") in view of U.S. Patent No. 6,817,414 to Lee *et al.* (hereinafter "*Lee*") and U.S. Patent No. 7,166,560 to Still *et al.* (hereinafter "*Still*").
- Claims 42-48, 55-59 and 61 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Nguyen* in view of *Lee* and *Still*, and further in

view of U.S. Patent No. 4,829,100 to Murphey, *et al.* (hereinafter "*Murphey*").

- Claims 42-48, 55-59, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Nguyen* in view of *Lee* and *Still*, and further in view of U.S. Patent No. 5,192,615 to McDougall *et al.* (hereinafter "*McDougall*").
- Claims 42-61 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Nguyen* in view of *Lee* and *Still*, or over *Nguyen* in view of *Lee* and *Still*, further in view of *Murphey* or over *Nguyen* in view of *Lee* and *Still*, further in view of McDougall, and further in view of Patent Application No. WO 9425079A1 to Mikos *et al.*, (related to 6,689,608) (hereinafter "*Mikos*").

The primary rejection over the pending claims is over *Nguyen* in view of *Lee* and *Still*. The Final Office Action dated February 25, 2011 states clearly that "*Lee* is a secondary reference which is relied upon to show that polyglycolic-acid is **suitable** for use as acid releasing treatment chemical." (Final Office Action at pg. 5, emphasis in original). With regard to *Still*, the Office Action dated November 4, 2010 states that *Still* is relied upon to show that solid acid precursors (such as lactides and glycolides, etc.) are known to be useful as delayed release acid producers. (11/4/2010 Office Action at pg. 6-7). Appellants do not dispute that both *Lee* and *Still* teach acid precursor materials.

The 11/4/2010 Office Action, to which the Final Office Action refers, relies on *Nguyen* as teaching that a "treatment chemical, which may be in particulate form or coated upon (*i.e.* coated upon the particulate) or in a substrate (See column 3, lines 43-44). Appellants disagree. *Nguyen* discloses that a generic "treatment chemical" may be stuck onto a particulate with a tackifying agent and optionally may be coated thereover with a resin. *Nguyen* also discusses the possibility that a liquid treatment chemical may be adsorbed onto a particulate and then coated with the tackifying agent and or resin. However, *Nguyen* does not teach that it might be desirable to render an acid releasing precursor into liquid form and then to coat that substance onto a particulate. There is no reason one of ordinary skill would

have read the combination of *Nguyen* in view of *Lee* and *Still* and concluded that an acid-releasing solid, once rendered coatable, would continue to act as an acid-producer down hole.

*Nguyen*, *Lee*, and *Still*, taken together, do not disclose “combining an acid-releasing degradable material with a solvent or a plasticizer to create a coating solution” and then coating that solution “on-the-fly” as required by independent claim 42, or “combining an acid-releasing degradable material with a plasticizer to create a coating solution” and then coating that solution “on-the-fly” as required by independent claim 55. Thus, *Nguyen*, *Lee*, and *Still* cannot form a prima facie case of obviousness with respect to claims 42 or 55. Accordingly, Appellants respectfully requests withdrawal of this rejection with respect to claims 42-48 and 55-60.

Independent claim 49 is rejected over the combination of *Nguyen*, *Lee*, *Still*, and *Mikos*. However, Appellants assert that independent claim 49, and the claims that depend therefrom are allowable for at least the reasons stated above with regard to the combination of *Nguyen*, *Lee*, and *Still*. The Office Action relies on *Mikos* for its alleged teaching of certain degradable synthetic polymers and noted that “it is well known in the art that all these polymers hydrolyze with release of an acid.” (11/4/2010 Office Action at p. 12). Appellants note that *Mikos* is directed towards medical devices, but as to the issue of what is “well known in the art,” the art of medical devices is not the art at issue. (*Mikos* Abstract). Thus, it is not surprising that *Mikos* does not disclose at least “combining an acid-releasing degradable material with a solvent or a plasticizer to create a coating solution” as required by independent claims 42 or 49, or “combining an acid-releasing degradable material with a plasticizer to create a coating solution” as required by independent claim 55. *Mikos* does not seek to make a degradable material coatable, but rather seeks to use a solid degradable material as “scaffolding” for tissue growth. (*Mikos* at col. 4, l. 66 – col. 5, l. 3).

As to the remaining secondary references, *Murphey* and *McDougall*, neither cures the deficiencies noted above. The Office Action relied on *Murphey* for its alleged teaching that a particulate “can be coated rapidly and continuously by admixing in a stream (on-the-fly) . . . instead of batch mixing which requires a period of time...” (See 11/4/2010 Office Action at pg. 10). And the Office Action

relied on *McDougall* for its alleged teaching of adding a friction reducing agent such as polyacrylamide or alcohol to the fluid suspension of *Nguyen*. (See 11/4/2010 Office Action at pg. 11). Thus, neither *Murphey* nor *McDougall* supply what is lacking from *Nguyen*, *Lee*, and *Still*.

### **CONCLUSION**

In light of the above remarks, Appellants respectfully request reconsideration and withdrawal of the outstanding rejections. Appellant further submits that the application is in condition for allowance, and earnestly solicits timely notice of the same.

Appellants submit with this Pre-Appeal Brief Request for Review a fee for a Notice of Appeal in the amount of \$540.00. Appellants believe that no additional fees are due in association with this Request. Should the Commissioner deem that any fees are due, including any fees for extensions of time, Appellants respectfully request that the Commissioner accept this as a Petition Therefore, and direct that any additional fees be charged to McDermott Will & Emery's Deposit Account No. 500417, Order Number 086108-0180.

Respectfully submitted,

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